Mini-implant supported canine retraction with micro-osteoperforation: A split-mouth randomized clinical trial

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Abstract: OBJECTIVES: To investigate, using a split-mouth randomized clinical design, the effect of micro-osteoperforation (MOP) on mini-implant supported canine retraction using fixed appliances. MATERIALS AND METHODS: Thirty subjects (seven males and 23 females) with a mean age of 22.2 (3.72) years were randomized into three canine retraction groups: Group 1 (MOP 4-weekly maxilla/8-weekly mandible; n = 10); Group 2 (MOP 8-weekly maxilla/12-weekly mandible; n = 10) and Group 3 (MOP 12-weekly maxilla/4-weekly mandible; n = 10) measured at 4-week intervals over 16 weeks. Subjects also completed pain (5-point Likert scale) and pain impact (Visual Analogue Scale) questionnaires. The primary outcome was the amount of canine retraction over 16 weeks at MOP (experimental) and non-MOP (control) sites. RESULTS: Mean overall canine retraction was 4.16 (1.62) mm with MOP and 3.06 (1.64) mm without. After adjusting for differences between jaws, all MOP groups exhibited significantly higher canine distalization than the control group: 0.89 mm more (95% confidence interval [CI] = 0.19 to 1.59 mm; P = .01) in the MOP-4 group, 1.08 mm more (95% CI = 0.49 to 1.68 mm; P = .001) in the MOP-8 group and 1.33 mm more (95% CI = 0.55 to 2.10 mm; P = .002) in the MOP-12 group. All subjects reported pain associated with MOP with 60% classifying it as moderate and 15% severe. The main impact of this reported pain was related to chewing and speech. CONCLUSIONS: MOP can increase overall mini-implant supported canine retraction over a 16-week period of observation but this difference is unlikely to be clinically significant.

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Mini-implant supported canine retraction with micro-osteoperforation: a split-mouth exploratory randomized clinical trial

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Color Figures – no

ABSTRACT

Objectives: This split-mouth randomized clinical study at the University of Malaya investigated the effect of micro-osteoperforation (MOP) on mini-implant supported canine retraction using fixed appliances. **Material and Methods:** Thirty subjects (7 males and 23 females) mean age 22.2 (3.72) years were randomized into three canine retraction groups: Group 1 (MOP 4-weekly maxilla/8-weekly mandible; n=10); Group 2 (MOP 8-weekly maxilla/12-weekly mandible; n=10) and Group 3 (MOP 12-weekly maxilla/4-weekly mandible; n=10) measured at 4-week intervals over 16-weeks. Subjects also completed pain (5-point Likert scale) and pain impact (Visual Analogue Scale) questionnaires. Primary outcome was amount of canine retraction over 16-weeks at MOP (experimental) and non-MOP (control) sites. **Results:** There were no significant differences between groups for baseline characteristics and no losses to follow-up. Mean overall canine retraction was 4.16 (1.62) mm with MOP and 3.06 (1.64) mm without. After adjusted for differences between jaws, all MOP groups exhibited significantly higher canine distalization than the control group: 0.89 mm more (95% Confidence Interval [CI]=0.19 to 1.59 mm; P=0.01) in the MOP-4 group, 1.08 mm more (95% CI=0.49 to 1.68 mm; P=0.001) in the MOP-8 group and 1.33 mm more (95% CI=0.55 to 2.10 mm; P=0.002) in the MOP-12 group. All subjects reported pain associated with MOP with 60% classified as moderate and 15% severe. The main impact of this reported of this pain related to chewing and speech. **Conclusions:** MOP can increase overall mini-implant supported canine retraction over a 16-week period of observation but this difference is unlikely to be clinically significant.

Key words: Accelerated tooth movement; mini-implant facilitated canine retraction; micro-osteoperforation

INTRODUCTION

A number of innovations have been described over recent years that aim to reduce orthodontic treatment time with fixed appliances [1]. Amongst these, surgical disruption of alveolar bone continuity has been suggested to facilitate the acceleration of orthodontic tooth movement [2]. Although the biological and clinical effects of surgical procedures on the alveolus during orthodontic treatment are poorly understood, surgery will induce a localized inflammatory response, which encourages local recruitment and stimulation of osteoclasts and increased remodeling. However, the evidence base relating to the efficiency of surgical-assisted orthodontics is currently small and associated with potential bias in many of the studies that have been performed to date, with more clinical trials needed [3].

Micro-osteoperforation (MOP) is one of the least invasive surgical techniques described for use in conjunction with orthodontic treatment. It involves the production of multiple trans-mucosal perforations within alveolar bone, sited in close proximity to the region of desired tooth movement and in specific configurations, depending upon the tooth movement required [4]. To date, the evidence base for MOP is small and contradictory, with some early data derived from animal models [5] and a single clinical trial in humans [6] demonstrating significant increases in rates of orthodontic tooth movement in conjunction with this technique. However, more recent evidence has been less encouraging, suggesting that rates of tooth movement are not altered in the presence of MOP [7]. Moreover, there is currently no evidence regarding the efficiency of this technique over the whole period of orthodontic treatment.

A better understanding of the clinical effectiveness of MOP is therefore desirable in orthodontics. We have investigated MOP using mini-implant supported canine retraction with fixed appliances. This split-mouth randomized prospective study focused on canine retraction with in the maxilla and mandible following the extraction of first premolar teeth, and the effects of multiple MOP carried out at specific time-points during a 16-week period of observation. In addition, feedback was also collected from participants relating to their experience of MOP during treatment.

MATERIAL AND METHODS

Trial design

This was a single-centre prospective randomized split-mouth clinical trial registered at ClinicalTrials.gov (DF CD1412/0089P). Ethical approval was obtained from the Medical Ethics Committee, University of Malaya (Malaysia) (DF CD1301/0009).

Participants, setting and eligibility criteria

Participants were recruited from subjects attending the Department of Orthodontics at the University of Malaya. Eligibility criteria included: (1) aged 18 years and above at start of treatment; (2) molar relationship either class I, < ½ unit class II or class III; (3) extraction of all four first premolar teeth as part of the orthodontic treatment; (4) maximum anchorage required using a mini-implant; (5) no systemic disease; (6) good oral hygiene and (7) no periodontal disease. Participants were excluded if they had significant vertical skeletal discrepancies, systemic diseases requiring long-term antibiotic use, phenytoin, cyclosporin, anti-inflammatory drugs, bisphosphonates, systemic corticosteroids or calcium channel blockers, poor oral hygiene for >2 visits or active periodontal disease.

Interventions

Participants were fitted with a pre-adjusted edgewise fixed appliance (3M Unitek, Monrovia, California USA) MBT prescription and 0.022 x 0.028-inch slot. A standardized six-weekly archwire sequence of 0.014-inch, 0.018-inch, 0.017 x 0.025-inch nickel titanium (NiTi) (3M Nitinol SuperElastic) was used for alignment, followed by a working archwire of 0.018 x 0.025-inch Stainless Steel (S/S) (GAC PAK Stainless Steel ACCUFORM®) used to minimize binding and friction during canine retraction [7]. Orlus® (Ortholution.com) 1.6 mm diameter mini-implants were placed under local anesthesia in a buccal position between the first permanent molar and second premolar and ligated directly to the first molar for anchorage. Canine retraction was carried out on the working archwire using 3M Unitek AlastiK™ elastomeric chain, force 140-200 grams (measured directly using a Correx Force Tension gauge, Haag-Streit Diagnostics, Switzerland) placed directly to the mini-implant posteriorly (as a fixed point of anchorage) and the canine bracket anteriorly. Canine retraction was commenced one visit following placement of the working archwire. At the randomized experimental sites, three separate MOPs were made directly through the buccal mucosa adjacent to the extraction site in a vertical direction 2 mm apart and 3 mm depth (measured using a rubber stopper) using an Orlus® screw (Ortholution.com) width 1.6 mm and length 6 mm (Figure 1A, B). After haemostasis was achieved using a cotton pellet and local pressure, paracetamol (1000 mg) was prescribed to be taken as necessary.

Post-operative pain and the impact of this pain on daily function was evaluated for each subject using a self-administrated questionnaire. This questionnaire evaluated overall pain intensity based on

a 5-point Likert scale throughout the study period and the impact of any pain on daily function based on a Visual Analogue Scale. [8,9]

Sample Size Calculation

Sample size calculation was based upon a previous trial investigating monthly canine retraction rate using power chain with conventional-ligated brackets over a three-month period (mean= 0.84 mm/month; SD=0.21 mm/month). Assuming the smallest difference requiring detection in canine retraction velocity to be 0.25 mm/month (30% increase) using a paired t-test, alpha level of 0.05 and power of 80% with an intra-cluster correlation coefficient of 0.5 [8]10 mouth sides would be needed per trial arm, giving a total of 30 mouth sides (15 patients) overall. Another 3 patients were added to account for possible drop-outs.

Randomization

Randomized block sampling was carried out using RANDOM.ORG online software to allocate participants into three intervention groups on a 1:1:1 basis. The three intervention groups consisted of different timed intervals of MOP during mini-implant facilitated canine retraction over the 16-week period of observation: Group 1 (4-weekly in the maxilla, MF-MOP-4; 8-weekly in the mandible, MF-MOP-8); Group 2 (8-weekly in the maxilla, MF-MOP-8; 12-weekly in the mandible, MF-MOP-12) and Group 3 (12-weekly in the maxilla, MF-MOP-12; 4-weekly in the mandible, MF-MOP-4). A simple randomization method drawing lots was employed to assign side of the maxilla and mandible to MOP intervention, while the opposing side served as the split-mouth control.

Data Collection

Data collection took place over a period of 16-weeks following the start of mini-implant facilitated canine retraction. At each 4-weekly review the power chain was replaced and the distance from the central point of the canine bracket to the superior margin of the mini-implant (maxilla) and the inferior margin of the mini-implant (mandible) and the distance from the canine cusp tip to the mesio-buccal groove of the first molar was clinically measured using electric digital calipers (accurate to 0.01 mm). MOP was carried out at the experimental sites according to randomized intervention group. A self-administered questionnaire was obtained from each subject at 16-weeks.

Outcomes

Primary outcome was amount of canine retraction achieved over the 16-week observation period at MOP (experimental) and non-MOP (control) sites. Secondary outcomes included amount of canine retraction associated with different MOP intervals, subject-reported pain and the impact of MOP on daily function during the trial period. The time intervals for MOP were selected based upon histochemical studies suggesting that osteoclast recruitment peaks at 4-weeks and then reduces gradually between week 8-12 following initiation of tooth movement [9].

Error of the method

Intra-observer and inter-observer calibration was conducted for canine retraction measurement [10] with a random error of 0.049 mm for inter-observer evaluation and 0.020 mm for intra-observer; whilst systematic error was 0.045 mm for the inter-observer evaluation and 0.020 mm for the intra-observer. Both errors were small and not significant ($P<0.05$).

Blinding

It was not possible to blind clinicians and subjects to allocated intervention site. However, all data were coded before processing and analysis, ensuring blinding at this stage of the study.

Statistical Analysis

Descriptive statistics were calculated including means and standard deviation (SD) after checking distribution of the trial outcome. Crude differences among experimental and control groups were calculated by one-way analysis of variance. Additionally, linear regression was used with robust standard errors taking into account clustering of canines within each patient. Initially, the administered intervention and possible confounders (age, sex, and jaw) were used in univariable models with canine distalization as the dependent variable. Afterwards, all variables with $P \leq 0.20$ were added in a multivariable model with the administered intervention to calculate adjusted estimates and their 95% Confidence Intervals (CI). ANOVA testing was also employed to test association of pain intensity for the three intervals of MF-MOP. Pairwise multiple comparison was performed with Bonferroni test to detect the mean pain differences between different intervals. Chi-Square test was employed to test

association of impact of pain on daily functions for the three intervals of MF-MOP. Analyses were run in Stata 14.2 (StataCorp, College Station, TX) and SPSS 23.0 (SPSS Inc., Chicago, USA) with a two-sided P ≤ 0.05 considered significant in all cases.

RESULTS

A CONSORT diagram showing subject flow through the trial is shown in Figure 2. Thirty subjects were enrolled into the study between September 2014 and March 2016 with data collection complete by March 2017 and no dropouts. A total of 10 subjects were allocated to each Group 1-3. The total randomized sample consisted of 7 males and 23 females had a mean age of 22.2 years (SD of 4.00).

Over the 16-week observation, the mean overall canine retraction was 3.06 mm (SD=1.64 mm) in the untreated control group and 4.16 mm (SD=1.62 mm) in the MOP groups. Specifically, the mean canine retraction was 3.96 mm (SD=1.71 mm) in the MOP-4 group, 4.15 mm (SD=1.40 mm) in the MOP-8 group, and 4.39 mm (SD=1.78) in the MOP-12 group, with significant differences among groups (Table 1). Initial regression analysis indicated that apart from the experimental group, jaw (maxilla versus mandible) significantly affected canine retraction (Table 2). After taking this confounder into consideration, all MOP groups exhibited significantly higher canine distalization than the control group: 0.89 mm more (95% CI=0.19 to 1.59 mm; P=0.01) in the MOP-4 group, 1.08 mm more (95% CI=0.49 to 1.68 mm; P=0.001) in the MOP-8 group, and 1.33 mm more (95% CI=0.55 to 2.10 mm; P=0.002) in the MOP-12 group. Finally, upper canines were distalized 0.94 mm more (95% CI=0.26 to 1.62 mm; P=0.008) during the 16-week observation period than lower canines.

All subjects returned completed pain intensity questionnaires and all reported pain associated with MOP. In those receiving MF-MOP-4, 60% reported moderate (score 2/5) and 15% reported severe (score 3/5) pain in both the maxilla and mandible. In contrast, the majority reported only mild (score 1/5) pain for MF-MOP-8 and MF-MOP-12 sites (70% and 75%, respectively). MF-MOP-4 site demonstrated the highest mean pain score of 1.75 (0.72) followed by a similar mean pain score for MF-MOP-8 and MF-MOP-12 of 1.35 (0.59) and 1.30 (0.57), respectively. The main reported impact of pain following MOP related to chewing and speech. However, the impact on general activities, including mood and social interaction were not statistically significant (P>0.05). Overall, pain associated with MOP, regardless of the interval produced some effect on participants daily activities with the exception of sleep.

DISCUSSION

Main findings in the context of existing evidence

This trial has demonstrated that MOP is able to significantly increase overall mini-implant supported canine retraction in the maxilla and mandible over a 16-week period of time in combination with elastomeric power chain and fixed appliances. This is in agreement with a previous split-mouth prospective investigation, although this study only reported on maxillary canine retraction and demonstrated a higher mean difference of 0.63 mm retraction per month in the presence of MOP compared to the 0.28 mm per month (average of the three MOP groups from Table 2 and adjusted per 4 weeks) found in the present study [6]. More recently, a further study has found no evidence that MOP can increase rates of canine extraction [7]. In our study, the canine retraction achieved over the 16-week period of observation is also below that found using other forms of more invasive surgical intervention [3,11]. Overall, the increased retraction achieved using MOP is probably not clinically significant and therefore it is difficult to justify the increased patient burden associated with this intervention as a means of reducing orthodontic treatment time.

Some possible reasons for the differences observed in various investigations might be the different surgical techniques being used, the specific mechanics of tooth movement investigated, the method of measurement and also measurement reference points. Nickel-titanium coil closing springs were used in the original study, which might be expected to provide a more consistent force of retraction [6]. However, elastomeric power chain is a routinely used and effective method of space closure used in many clinical situations [12] and in this study, power chain from a specific research inventory stored under ideal and constant conditions was used. Moreover, the split-mouth study design, routine replacement every 4 weeks and measurement to apply a standardized force all contributed towards minimising variation in space closure mechanics.

Importantly, this investigation also showed no significant differences in overall canine retraction associated with the three different MOP intervals, suggesting that any regional acceleration induced by MOP has an effect that extends for at least 12 weeks. Intervals shorter than 4 weeks and longer than 12 weeks were not included because osteoclast recruitment has been found to peak at 4 weeks and gradually reduce by 12 weeks [9]. Although comparison of MOP intervals within individuals did demonstrate significantly increased tooth movement in the MF-MOP-12 group when compared to the

two other intervals, further studies will be required to suggest that 12 weekly MOP is recommended to provide optimal treatment effects. Clearly, it is in the interest of the patient to keep any surgical interventions to a minimum.

Canine retraction was investigated over a 16-week period of observation, which only constitutes a small portion of the overall treatment for these extraction cases. We cannot comment on the potential effect of MOP during orthodontic alignment or other stages of treatment, but if it is assumed that the biological response to different types of tooth movement are similar and that the overall response is not influenced by MOP intervals, extrapolating our findings to an average treatment duration of 18 months is suggestive of a possible reduction in treatment time of up to 30 per cent. However, this would be quite an assumption and would need to be substantiated with more evidence from prospective studies investigating the effect of MOP over the entire period of treatment. It should be stated that the few prospective studies that have investigated the effect of specific fixed appliances or adjuncts designed to reduce treatment time rarely find any differences over the long-term [13,14].

This investigation also found less reported pain for the MF-MOP-8 and MF-MOP-12 groups as compared to the MF-MOP-4 in relation to the overall observation period, which is consistent with keeping surgical interventions to a minimum for the benefit of the patient. However, this reported overall pain perception was subject to recall bias as the data was obtained at the end of the observation period. Indeed, a possible reason for the less painful perception with MF-MOP-8 and MF-MOP-12 intervals compared to MF-MOP-4 could be due to the phenomenon of a gradual decline in memory of pain experience after a longer duration. However, pain during fixed appliance therapy has been reported as a major reason for discontinuation of orthodontic treatment and can impact on general daily activities, including eating, leisure, social life, sleep and exercise, albeit to a mild degree [15]. Interestingly, we found that almost all daily activities except sleep were impacted following MOP, which is a further reason to keep this intervention to a minimum.

Limitations of the study

This study has a number of limitations. Direct clinical measurement of canine retraction may be less accurate than measurement from dental study casts or using three-dimensional superimposition and the use of elastomeric chain may result in less consistency of space closure forces between subjects. In addition, this study only investigated canine retraction over a 16-week period of time and therefore

does not represent the entirety of orthodontic treatment. Pain data was only collected at the end of the study and as this was only a secondary outcome, the trial is likely to be underpowered for pain analysis. However, this prospective randomized split-mouth exploratory investigation of MOP during canine retraction with fixed appliances does add to the evidence base and should form the basis of further longer-term prospective research.

CONCLUSIONS

- MOP was associated with statistically significant increased overall canine retraction of 1.1 mm over a 16-week period of observation;
- There were only small differences in tooth movement when intervals of 4, 8 and 12 week MOP were used;
- Moderate pain was associated with MOP at 4 week intervals whilst only mild pain was perceived for intervals of 8 and 12 weeks; and
- The increased canine retraction achieved using MOP over a 16-week period is unlikely to be clinically significant.

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FIGURE LEGENDS

Figure 1 MOP placement (A) Site and (B) Clinical application with the mini-implant

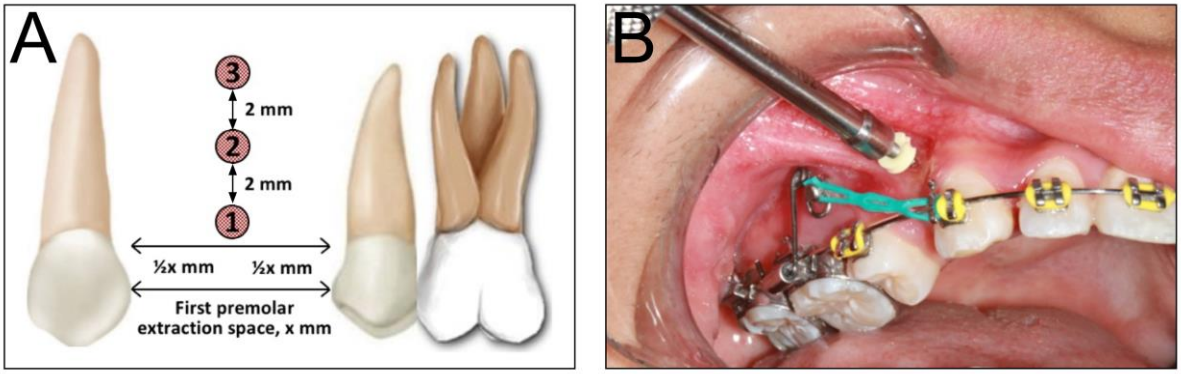


Figure 2 CONSORT diagram showing the flow of subjects through the trial

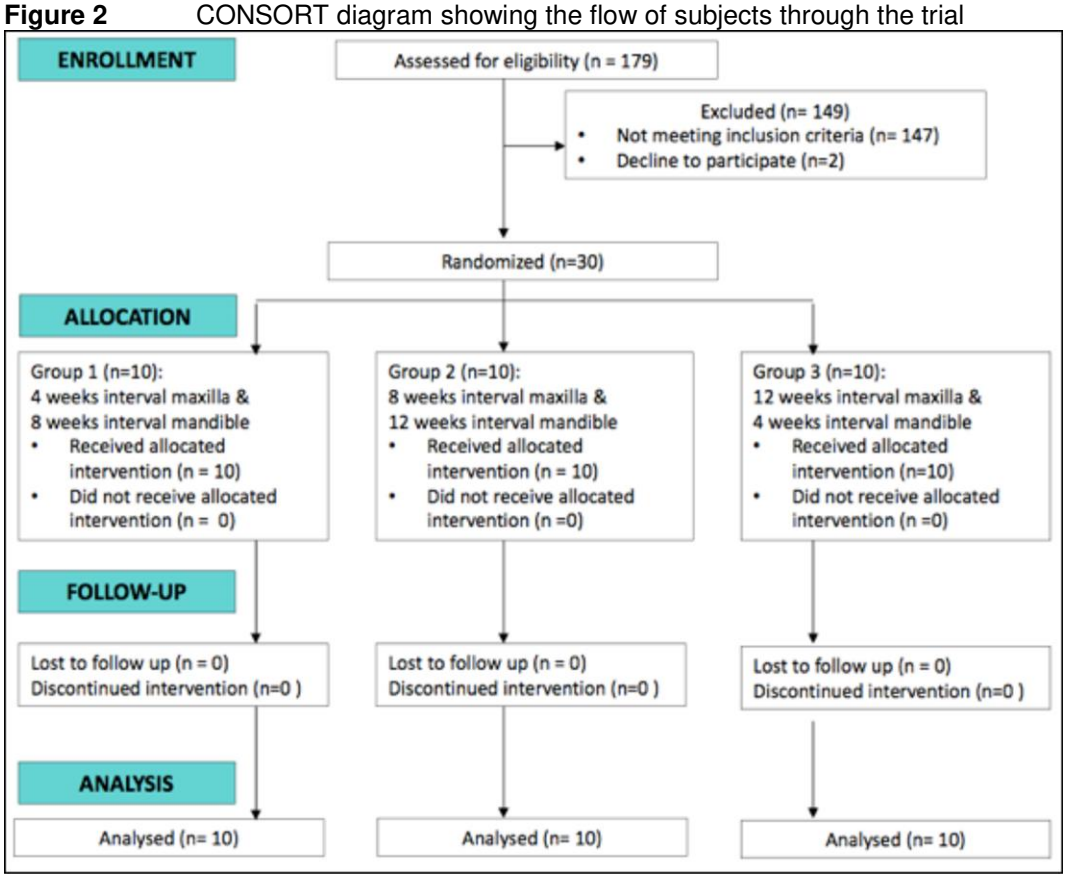
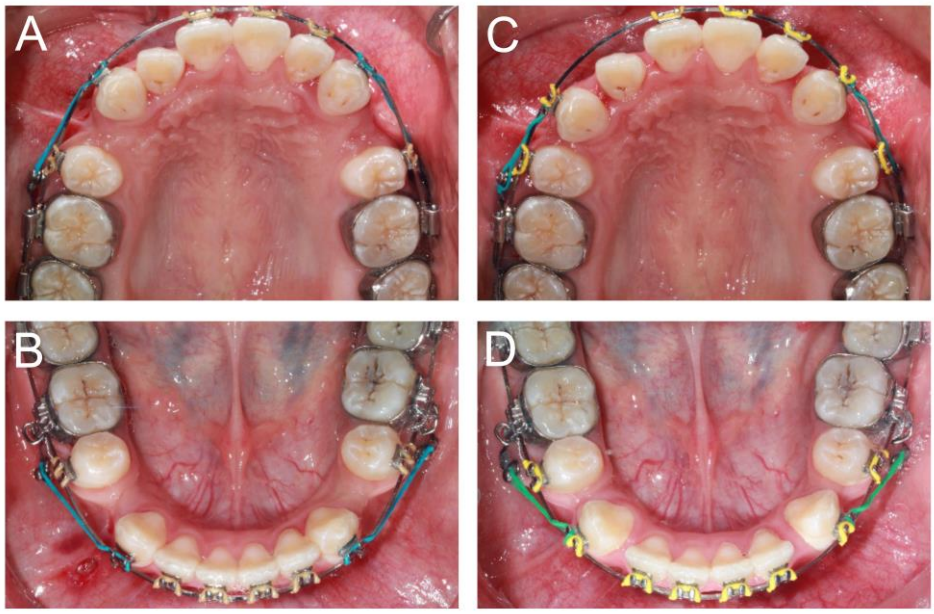


Figure 3 Maxillary and mandibular dental arches from a representative subject within the trial (A, B) Start of canine retraction; (C, D) At 16 weeks of canine retraction. MOP was randomized to the upper right and lower left quadrants in this subject.



TABLES

Table 1. Descriptive statistics of the trial's outcome

Group	N	Mean (SD)	P
Control	60	3.06 (1.64)	0.004
MOP-4	20	3.96 (1.71)	
MOP-8	20	4.15 (1.40)	
MOP-12	20	4.39 (1.78)	

MOP, micro-osteoperforation; SD, standard deviation

Table 2. Regression analysis with amount of canine distalization as dependent variable

		Univariable			Multivariable*	
Factor	**Group**	**b (95% CI)**	**P**		**b (95% CI)**	**P**
Age	Per year	-0.02 (-0.14 to 0.09)	0.66		NT	
Sex	Female	*Referent*			NT	
	Male	0.21 (-0.56 to 0.97)	0.58		NT	
Jaw	Mandible	*Referent*			*Referent*	
	Maxilla	0.94 (0.27 to 1.61)	0.007		0.94 (0.26 to 1.62)	0.008
Group	Control	*Referent*				
	MOP-4	0.89 (0.20 to 1.59)	0.01		0.89 (0.19 to 1.59)	0.01
	MOP-8	1.08 (0.49 to 1.67)	0.001		1.08 (0.49 to 1.68)	0.001
	MOP-12	1.33 (0.56 to 2.10)	0.001		1.33 (0.55 to 2.10)	0.002x

CI, confidence interval; MOP, micro-osteoperforation; NT, not tested
* An interaction term of experimental group with jaw (P=0.46) was tested and ultimately dropped.

QUESTIONNAIRE INVESTIGATIONG PATIENT'S PERCEPTION ON PAIN INTENSITY AND IMPACT OF PAIN ON DAILY ACTIVITIES AFTER RECEIVING MICRO-OSTEOPERFORATION.

TITLE :- Mini-implant supported canine retraction with micro-osteoperforation: a split-mouth exploratory randomized clinical trial

Name :-
Registration Number :-

1. For the following questions, please mark 'X' to denote the pain intensity level in the boxes provided. Please provide separate pain response for left and right side in the upper jaw and lower jaw.

After receiving micro-osteoperforation for the past 4 months, please tick the boxes to indicate your overall pain perception during the course of your treatment. Read the following definitions on the pain score to help you to answer the questions below:-

No Pain : No pain
Mild pain : Minor discomfort at the micro-osteperforation side
Moderate pain : Pain that is bearable and **able to chew** normally at the micro-osteoperforation area.
Severe pain : More intense pain but the pain that does **not disturb sleep** and **unable to che**w at the micro-osteoperfortion area
Very severe pain : Extreme unberable pain that **disturbs sleep**

Upper Right Jaw

0 = No pain	1 = Mild pain	2 = Moderate pain	3 = Severe pain	4 = Very severe pain

Lower right jaw

Upper left jaw

0 = No pain	1 = Mild pain	2 = Moderate pain	3 = Severe pain	4 = Very severe pain

Lower left jaw

2. For the following questions, please indicate the impact of any pain on the following daily activities using the 10-point scale:

(i) General activities (chewing food, speaking)

0	1	2	3	4	5	6	7	8	9	10
None										Complete

(ii) Sleep

0	1	2	3	4	5	6	7	8	9	10
None										Complete

(iii) Mood/Emotion

0	1	2	3	4	5	6	7	8	9	10
None										Complete

(iv) Social interaction

0	1	2	3	4	5	6	7	8	9	10
None										Complete

(v) Daily routine (going to work)

0	1	2	3	4	5	6	7	8	9	10
None										Complete

Thank you for your kind co-operation